ATTACHMENT 3

510(K) SUMMARY OF SAFETY & EFFECTIVENESS

MAR 2 9 2001

Official Contact	David J. Vanella Manager, Regulatory Affairs/Product Assurance Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668
Classification Reference	21 CFR 868.5905
Product Code	BZD – Non-Continuous ventilator
Common/Usual Name	CPAP System
Proprietary Name	Respironics REMstar Plus CPAP System
Predicate Device(s)	Respironics Solo CPAP System (K961626) Respironics Aria LX CPAP System (K993307) Fisher & Paykel Electronics, Humidifier, Respiratory Gas (Direct Patient Interface)(K915460)
Reason for submission	Modified design, additional accessories.

Substantial Equivalence

The modified device has the following similarities to the previously cleared predicate device:

- ❑ Same intended use.
- ❑ Same operating principle.
- ❑ Same technology.
- ❑ Same manufacturing process.

Design verification tests were performed on the REMstar Plus CPAP System as a result of the risk analysis and product requirements. All tests were verified to meet the required acceptance criteria. Respironics has determined that the modifications have no impact on the safety and effectiveness of the device. In summary, the device described in this submission is substantially equivalent to the predicate device.

The modified device complies with the applicable standards referenced in the Guidance for FDA Reviewers and Industry "Guidance for the Content of premarket Submissions for Software Contained in Medical Devices", May 1998.

Intended Use

The REMstar Plus CPAP System delivers positive airway pressure therapy for the treatment of Obstructive Sleep Apnea only for use in the home or hospital/institutional environment on adult patients.

Device Description

The REMstar Plus Continuous Positive Airway Pressure (CPAP) System is a smaller and lighter micro processor-controlled, blower-based system that generates positive airway pressures from 4 to 20 cmH_2O. The device is intended for use with a patient circuit that is used to connect the device to the patient interface (mask). The CPAP device may also be used with the REMstar Heated Humidifier that has been designed to be compatible with the CPAP and controlled from the CPAP. The basic functional and performance characteristics of the REMstar Plus CPAP device includes all of the patient friendly designs of the predicate device (Solo CPAP System K961626). The basic functional and performance characteristics of the REMstar Heated Humidifier are similar to the predicate device (Humidifier, Respiratory Gas (Direct Patient Interface) K915460).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 9 2001

Mr. David J. Vanella
Respironics, Inc.
1001 Murry Ridge Lane
Murrysville, PA 15668-8550

Re: K010263
Trade Name: REMstar Plus CPAP System
Regulatory Class: II (two)
Product Code: BZD & BTT
Dated: February 26, 2001
Received: March 1, 2001

Dear Mr. Vanella:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010263

Device Name: Respironics® REMstar Plus CPAP System

Intended Use/Indications for Use

The REMstar Plus CPAP System delivers positive airway pressure therapy for the treatment of Obstructive Sleep Apnea only.

Environment of Use/Patient Population

For use in the home or hospital/institutional environment on adult patients.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K010263